Device Evaluation, Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850.

§814.106 HDE amendments and resubmitted HDE's.

An HDE or HDE supplement may be amended or resubmitted upon an applicant's own initiative, or at the request of FDA, for the same reasons and in the same manner as prescribed for PMA's in §814.37. The timeframes and extension of review times set forth in §814.37 for PMA's shall also be applicable to HDE's.

§814.108 Supplemental applications.

After FDA approval of an original HDE, an applicant shall submit supplements in accordance with the requirements for PMA's under §814.39, except that a request for a new indication for use of a HUD shall comply with the requirements set forth in §814.110.

§814.110 New indications for use.

(a) An applicant seeking a new indication for use of a HUD approved under this subpart H shall obtain a new designation of HUD status in accordance with §814.102 and shall submit an original HDE in accordance with §814.104.

(b) An application for a new indication for use made under §814.104 may incorporate by reference any information or data previously submitted to the agency under an HDE.

§814.112 Filing an HDE.

(a) The filing of an HDE means that FDA has made a threshold determination that the application is sufficiently complete to permit substantive review. Within 45 days from the date an HDE is received by FDA, the agency will notify the applicant whether the application has been filed. FDA may refuse to file an HDE if any of the following applies:

(1) The application is incomplete because it does not on its face contain all the information required under §814.104(c);

(2) FDA determines that there is a comparable device available (other than another HUD approved under this subpart or a device under an approved IDE) to treat or diagnose the disease or condition for which approval of the HUD is being sought; or

(3) The application contains an untrue statement of material fact or omits material information.

(4) The HDE is not accompanied by a statement of either certification or disclosure, or both, as required by part 54 of this chapter.

(b) The provisions contained in §814.42(b), (c), and (d) regarding notification of filing decisions, filing dates, the start of the 180-day review period, and applicant's options in response to FDA refuse to file decisions shall apply to HDE's submitted under this subpart as well as to PMA's submitted under §814.20.

[61 FR 33244, June 26, 1996, as amended at 63 FR 5254, Feb. 2, 1998]

EFFECTIVE DATE NOTE: At 63 FR 5254, Feb. 2, 1998, §814.112 was amended by adding new paragraph (a)(4), effective Feb. 2, 1999.

§814.114 Timeframes for reviewing an HDE.

Within 180 days after receipt of an HDE that is accepted for filing and to which the applicant does not submit a major amendment, FDA will send the applicant an approval order, an approvable letter, or a not approvable letter (under §814.116), or an order denying approval (under §814.118).

§814.116 Procedures for review of an HDE.

(a) *Substantive review*. FDA will begin substantive review of an HDE after the HDE is accepted for filing under §814.112. FDA may refer an original HDE application to a panel on its own initiative, and shall do so upon the request of an applicant, unless FDA determines that the application substantially duplicates information previously reviewed by a panel. If the HDE is referred to a panel, the agency shall follow the procedures set forth under §814.44.

(b) *Approval order*. FDA will issue to the applicant an order approving an HDE if none of the reasons in §814.118 for denying approval of the application applies. FDA will approve an application on the basis of draft final labeling if the only deficiencies in the application concern editorial or similar minor deficiencies in the draft final labeling.